

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as introduced, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by

the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the board or department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the

forms to set forth specified information, as appropriate, with respect to practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and multiple prescribers.

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or prescriber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department.

(7) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 11159.2 of the Health and Safety Code
- 2 is amended to read:
- 3 11159.2. (a) Notwithstanding any other provision of law, a
- 4 prescription for a ~~Schedule II~~ controlled substance for use by a
- 5 patient who has a terminal illness shall meet the following
- 6 requirements:
- 7 (1) Contain the information specified in subdivision (a) of
- 8 Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words “11159.2 exemption.”

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient’s terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, “terminally ill” means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient’s illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient’s treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate~~ *prescription blanks or controlled substance prescription forms* in the practitioner’s possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order.* Except as provided in subdivisions (b) and (c) of this section, the order shall remain in effect until further order of the

1 court. Any practitioner possessing prescription-blanks *forms* in
2 violation of the order is guilty of a misdemeanor.

3 (b) The order provided by subdivision (a) shall be vacated if
4 the court or magistrate finds that the underlying violation or
5 violations are not supported by reasonable cause at a hearing held
6 within two court days after the practitioner files and personally
7 serves upon the prosecuting attorney and the law enforcement
8 agency that obtained the order, a notice of motion to vacate the
9 order with any affidavits on which the practitioner relies. At the
10 hearing, the burden of proof, by a preponderance of the evidence,
11 is on the prosecution. Evidence presented at the hearing shall be
12 limited to the warrant of arrest with supporting affidavits, the
13 motion to require the defendant to surrender ~~all triplicate~~
14 ~~prescription-blanks or controlled substance prescription forms~~
15 ~~and to prohibit the defendant from obtaining, ordering, or using~~
16 controlled substance prescription forms, with supporting
17 affidavits, the sworn complaint together with any documents or
18 reports incorporated by reference thereto which, if based on
19 information and belief, state the basis for the information, or any
20 other documents of similar reliability as well as affidavits and
21 counter affidavits submitted by the prosecution and defense.
22 Granting of the motion to vacate the order is no bar to
23 prosecution of the alleged violation or violations.

24 (c) The defendant may elect to challenge the order issued
25 under subdivision (a) at the preliminary examination. At that
26 hearing, the evidence shall be limited to that set forth in
27 subdivision (b) and any other evidence otherwise admissible at
28 the preliminary examination.

29 (d) If the practitioner has not moved to vacate the order issued
30 under subdivision (a) by the time of the preliminary examination
31 and he or she is held to answer on the underlying violation or
32 violations, the practitioner shall be precluded from afterwards
33 moving to vacate the order. If the defendant is not held to answer
34 on the underlying charge or charges at the conclusion of the
35 preliminary examination, the order issued under subdivision (a)
36 shall be vacated.

37 (e) Notwithstanding subdivision (d), any practitioner who is
38 diverted pursuant to Chapter 2.5 (commencing with Section
39 1000) of Title 7 of Part 2 of the Penal Code may file a motion to
40 vacate the order issued under subdivision (a).

1 (f) This section shall become operative on November 1, 2004.

2 SEC. 3. Section 11161.5 of the Health and Safety Code is
3 amended to read:

4 11161.5. (a) Prescription forms for controlled substance
5 prescriptions shall be obtained from security printers approved
6 by the ~~Board of Pharmacy~~ *Department of Justice*.

7 (b) The ~~Board of Pharmacy~~ *department* may approve security
8 printer applications after the applicant has provided the following
9 information:

10 (1) Name, address, and telephone number of the applicant.

11 (2) Policies and procedures of the applicant for verifying the
12 identity of the prescriber ordering controlled substance
13 prescription forms.

14 (3) Policies and procedures of the applicant for verifying
15 delivery of controlled substance prescription forms to
16 prescribers.

17 (4) (A) The location, names, and titles of the applicant's agent
18 for service of process in this state; all principal corporate officers,
19 if any; and all managing general partners, if any.

20 (B) A report containing this information shall be made on an
21 annual basis and within 30 days after any change of office,
22 principal corporate officers, or managing general partner.

23 (5) (A) A signed statement indicating whether the applicant,
24 principal corporate officers, or managing general partners have
25 ever been convicted of, or pled no contest to, a violation of any
26 law of a foreign country, the United States, or any state, or of any
27 local ordinance.

28 (B) The ~~applicant~~ *department* shall ~~also~~ *provide the applicant*
29 *with the means and direction to provide fingerprints and related*
30 *information*, in a manner specified by the ~~Board of Pharmacy~~
31 *department*, for the purpose of completing state ~~and~~, federal, or
32 foreign criminal background checks.

33 (C) *Any applicant described in subdivision (b) shall submit his*
34 *or her fingerprint images and related information to the*
35 *department, for the purpose of the department obtaining*
36 *information as to the existence and nature of a record of state,*
37 *federal, or foreign level convictions and state, federal, or foreign*
38 *level arrests for which the department establishes that the*
39 *applicant was released on bail or on his or her own recognizance*
40 *pending trial, as described in subdivision (l) of Section 11105 of*

1 the Penal Code. Requests for federal level criminal offender
2 record information *received by the department* pursuant to this
3 section shall be forwarded to the Federal Bureau of Investigation
4 *by the department*.

5 (D) *The department shall assess against each applicant a fee*
6 *determined by the department to be sufficient to cover all*
7 *processing, maintenance, and investigative costs generated from*
8 *or associated with completing state, federal, or foreign*
9 *background checks pursuant to this section with respect to that*
10 *applicant; the fee shall be paid by the applicant at the time he or*
11 *she submits fingerprints and related information to the*
12 *department.*

13 (E) *The department shall retain fingerprint impressions and*
14 *related information for subsequent arrest notification pursuant to*
15 *Section 11105.2 of the Penal Code for all applicants.*

16 ~~(c) Prior to approving a security printer application, the Board~~
17 ~~of Pharmacy shall submit a copy of the application to the~~
18 ~~Department of Justice; the Department of Justice may, within 30~~
19 ~~The department may, within 60~~ calendar days of receipt of the
20 application from the ~~Board of Pharmacy~~ applicant, deny the
21 security printer application.

22 ~~(d) The Board of Pharmacy or the Department of Justice~~
23 ~~department~~ may deny a security printer application on any of the
24 following grounds:

25 (1) The applicant, *any individual owner, partner, corporate*
26 *officer, manager, agent, representative, employee, or*
27 *subcontractor for the applicant, who has direct access,*
28 *management, or control of controlled substance prescription*
29 *forms, has been convicted of a crime. A conviction within the*
30 *meaning of this paragraph means a plea or verdict of guilty or a*
31 *conviction following a plea of nolo contendere. Any action*
32 *which a board is permitted to take following the establishment of*
33 *a conviction may be taken when the time for appeal has elapsed,*
34 *the judgment of conviction has been affirmed on appeal, or when*
35 *an order granting probation is made suspending the imposition of*
36 *sentence, irrespective of a subsequent order under the provisions*
37 *of Section 1203.4 of the Penal Code.*

38 (2) The applicant committed any act involving dishonesty,
39 fraud, or deceit with the intent to substantially benefit himself,
40 herself, or another, or substantially injure another.

1 (3) The applicant committed any act that would constitute a
2 violation of this division.

3 (4) The applicant knowingly made a false statement of fact
4 required to be revealed in the application to produce controlled
5 substance prescription forms.

6 (5) ~~The Board of Pharmacy or Department of Justice~~
7 *department* determines that the applicant failed to demonstrate
8 adequate security procedures relating to the production and
9 distribution of controlled substance prescription forms.

10 (6) ~~The Board of Pharmacy or Department of Justice~~
11 *department* determines that the applicant has submitted an
12 incomplete application.

13 (7) *As a condition for its approval as a security printer, an*
14 *applicant shall authorize the Board of Pharmacy or Department*
15 *of Justice to make any examination of the books and records of*
16 *the applicant, or to visit and inspect the applicant during*
17 *business hours, to the extent deemed necessary by the board or*
18 *department to properly enforce this section.*

19 (e) ~~The Board of Pharmacy~~ *department* shall maintain a list of
20 approved security printers and the ~~Board of Pharmacy~~
21 *department* shall make this information available to prescribers
22 and other appropriate government agencies, including the
23 ~~Department of Justice Board of Pharmacy.~~

24 (f) Before printing any controlled substance prescription
25 forms, a security printer shall verify with the appropriate
26 licensing board that the prescriber possesses a license and current
27 prescribing privileges which permits the prescribing of controlled
28 substances.

29 (g) Controlled substance prescription forms shall be provided
30 directly to the prescriber either in person, by certified mail, or by
31 a means that requires a signature signifying receipt of the
32 package and provision of that signature to the security printer.

33 (h) Security printers shall retain ordering and delivery records
34 in a readily retrievable manner for individual prescribers for three
35 years.

36 (i) Security printers shall produce ordering and delivery
37 records upon request by an authorized officer of the law as
38 defined in Section 4017 of the Business and Professions Code.

39 (j) (1) ~~The Board of Pharmacy or the Department of Justice~~
40 *department* may revoke its approval of a security printer for a

1 violation of this division or action that would permit a denial
2 pursuant to subdivision (d) of this section.

3 (2) When the ~~Board of Pharmacy or the Department of Justice~~
4 *department* revokes its approval, it shall notify the appropriate
5 licensing boards and remove the security printer from the list of
6 approved security printers.

7 ~~(k) Security printer applicants may appeal a denial or~~
8 ~~revocation by the Board of Pharmacy to the full board in a public~~
9 ~~meeting of the Board of Pharmacy.~~

10 SEC. 4. Section 11162.1 of the Health and Safety Code is
11 amended to read:

12 11162.1. (a) The prescription forms for controlled substances
13 shall be printed with the following features:

14 (1) A latent, repetitive “void” pattern shall be printed across
15 the entire front of the prescription blank; if a prescription is
16 scanned or photocopied, the word “void” shall appear in a pattern
17 across the entire front of the prescription.

18 (2) A watermark shall be printed on the backside of the
19 prescription blank; the watermark shall consist of the words
20 “California Security Prescription.”

21 (3) A chemical void protection that prevents alteration by
22 chemical washing.

23 (4) A feature printed in thermo-chromic ink.

24 (5) An area of opaque writing so that the writing disappears if
25 the prescription is lightened.

26 (6) A description of the security features included on each
27 prescription form.

28 (7) (A) Six quantity check off boxes shall be printed on the
29 form and the following quantities shall appear:

30 1-24

31 25-49

32 50-74

33 75-100

34 101-150

35 151 and over.

36 (B) In conjunction with the quantity boxes, a space shall be
37 provided to designate the units referenced in the quantity boxes
38 when the drug is not in tablet or capsule form.

39 (8) Prescription blanks shall ~~either (A)~~ contain a statement
40 printed on the bottom of the prescription blank that the

~~“Prescription is void if more than one controlled substance prescription is written per blank” or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the “Prescription is void if the number of drugs prescribed is not noted.”~~

(9) (A) The preprinted name, category of licensure, license number, ~~and~~ federal controlled substance registration number of the prescribing practitioner.

(B) *The privileges of a practitioner to prescribe any of the following controlled substances shall be preprinted beside the prescriber’s name and as designated in the prescriber’s certificate issued by the federal Drug and Enforcement Agency:*

(i) *Schedule II narcotic.*

(ii) *Schedule II nonnarcotic.*

(iii) *Schedule III narcotic.*

(iv) *Schedule III nonnarcotic.*

(v) *Schedule IV.*

(vi) *Schedule V.*

(10) A check box indicating the prescriber’s order not to substitute.

(11) *An identifying number assigned to the approved security printer by the Department of Justice.*

(12) *A physician assistant authorized by Section 3502.1 of the Business and Professions Code to issue a drug order may do so under his or her own name on prescription forms preprinted with the information required by Section 11162 that are in compliance with subdivision (d) of Section 3502.1 of the Business and Professions Code.*

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated

prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) (A) *Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber.*

(B) *Each designated prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by the prescriber's name.*

(4) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

~~(4)~~

(5) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

1 (5) Quantity of the controlled substance dispensed.

2 (6) ICD-9 (diagnosis code), if available.

3 (7) Date of issue of the prescription.

4 (8) Date of dispensing of the prescription.

5 (9) *Method of payment for prescription.*

6 (e) This section shall become operative on January 1, 2005.

7 SEC. 6. Section 11190 of the Health and Safety Code is
8 amended to read:

9 11190. (a) Every practitioner, other than a pharmacist, who
10 prescribes or administers a controlled substance classified in
11 Schedule II shall make a record that, as to the transaction, shows
12 all of the following:

13 (1) The name and address of the patient.

14 (2) The date.

15 (3) The character, including the name and strength, and
16 quantity of controlled substances involved.

17 (b) The prescriber's record shall show the pathology and
18 purpose for which the controlled substance was administered or
19 prescribed.

20 (c) (1) For each prescription for a Schedule II or Schedule III
21 controlled substance that is dispensed by a prescriber pursuant to
22 Section 4170 of the Business and Professions Code, the
23 prescriber shall record and maintain the following information:

24 (A) Full name, address, gender, and date of birth of the
25 patient.

26 (B) The prescriber's category of licensure and license number;
27 federal controlled substance registration number; and the state
28 medical license number of any prescriber using the federal
29 controlled substance registration number of a
30 government-exempt facility.

31 (C) NDC (National Drug Code) number of the controlled
32 substance dispensed.

33 (D) Quantity of the controlled substance dispensed.

34 (E) ICD-9 (diagnosis code), if available.

35 (F) Date of dispensing of the prescription.

36 (2) Each prescriber that dispenses controlled substances shall
37 provide the Department of Justice the information required by
38 this subdivision on a monthly basis in ~~either hardcopy or~~
39 ~~electronic form~~ *a format set by the Department of Justice.*

40 (d) This section shall become operative on January 1, 2005.

1 SEC. 7. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution for
3 certain costs that may be incurred by a local agency or school
4 district because, in that regard, this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the
6 penalty for a crime or infraction, within the meaning of Section
7 17556 of the Government Code, or changes the definition of a
8 crime within the meaning of Section 6 of Article XIII B of the
9 California Constitution.
10 However, if the Commission on State Mandates determines
11 that this act contains other costs mandated by the state,
12 reimbursement to local agencies and school districts for those
13 costs shall be made pursuant to Part 7 (commencing with Section
14 17500) of Division 4 of Title 2 of the Government Code.